detecting a change of the incident light or a change of a reflected light thereof when said resonance phenomenon is generated; and

recognizing an amount of medical substance contained in said sample on the basis of said change of the incident light or the reflected light.

25. (New) A method for measuring a medical substance according to Claim 24, wherein said resonance phenomenon is a surface plasmon resonance phenomenon.

26. (New) An apparatus according to Claim 16, wherein said resonance phenomenon is a surface plasmon resonance phenomenon.

27. An apparatus according to claim 17, wherein said resonance phenomenon is a surface plasmon resonance phenomenon.

REMARKS

This is in response to the Office Action of January 22, 1999 in which the Examiner:

(a) found claims 1 and 5 to be indefinite because the language "i.e. an antigen as an object to be measured" in line 4 is not clear as to whether the example is intended to be exemplary or limiting;

(b) found the language "detecting a condition for generating" the resonance phenomenon to be confusing;

(c) found claims 2 and 6 to be vague and confusing for the same reasons set forth above with respect to the recitation of "said condition for generating said resonance phenomenon is changed when a mixture of antibody...";

(d) found claims 1-12 to be anticipated by Batchelder (U.S. Patent 4,844,613), Finland (U.S. Patent 4,997,278), and Cush (Biosensors & Bioelectronics 8 ((1993), 347-353);

(e) found claims 1-8 to be anticipated by Finlan (U.S. Patent 5,047,213), and Shanks (U.S. Patent 4,810,658); and

(f) found claims 1-4 to be anticipated by Stewart (U.S. Patent 4,857,273).

Based on the following amendments and remarks, the application is deemed to be in condition for allowance and action to that end is respectfully requested.

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I. THE INVENTION

The present invention relates to a medical substance measuring apparatus in which a medical substance is measured by using a resonance phenomenon resonating with an evanescent wave and related to a medical substance sensor for use in the apparatus. A major feature of the present invention is that the medical substance to be measured by the apparatus is fixed to a resonance material as an antigen.

II. THE § 112 REJECTION SHOULD BE WITHDRAWN.

In the attached new set of claims, the objected expression of "detecting a condition for generating the resonance phenomenon" has been changed to -- a detecting means for detecting a change of an incident light which is made incident upon said resonance material to generate said resonance phenomenon or a change of a reflected light thereof -- in order to make it more concrete and clearer. It is also submitted that the other § 112 rejections are resolved in the new claims.

In the new claims 15 and 16, "the change of an incident light which is made incident upon said resonance material to generate said resonance phenomenon and its reflected light" is specified in a more concrete and clearer manner.

There is support for all of the new claims as demonstrated herein. Specifically, the fact that the condition for generating the resonance phenomenon is:

(1) "an incident angle of said incident light being made incident upon said resonance material when and intensity of the reflected light thereof is decreased" (Claim 15) is mentioned

in the Specification on page 3, line 13 to page 4, line 1, page 15, lines 8-27, page 20, lines 23-29, page 21, lines 1 to 12, etc.;

"a wavelength or a wave number of said reflected light when an intensity of said reflected light is decreased" (Claim 16) is on page 3, line 13 to page 4, line 1, page 7, lines 17 to 25, page 21, lines 1 to 12, page 21, lines 13 to 22, etc.;

"an intensity of said reflected light when the incident is made incident upon said resonance material with a predetermined incident angle" (Claim 17) is on page 20, lines 12 to 15, page 20, lines 23 to 29, etc.;

"an incident angle of said incident light when a phase of said reflected light is varied" is on page 4, lines 2 to 27, page 7, lines 17 to 25, page 21, lines 23 to page 22, line 1, etc.

Therefore, these new claims do not raise any new matter.

Further, new claims 24 and 25 are rewritten as method claims on the basis of old claims 2, 6 and 11. The content of new claims 24 and 25 are also supported by the specification as a whole, so that these claims also do not cause any new matter.

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III. THE NEWLY REVISED CLAIMS ARE CLEARLY PATENTABLE OVER THE PRIOR ART

As mentioned in the specification on page 4, line 28 to page 5, line 24, according to previously known methods, it has been tried to measure in a medical substance that an antibody is fixed to a resonance material, such as a metal thin film, and the medical substance (antigen) which is coupled to the antibody in a specific manner is detected directly. However, the medical substance contained in a body liquid, such as urine or blood, has a significantly small molecular weight; therefore, even if the medical substance is reacted with the antibody fixed to the resonance material (antigen-antibody reaction), the change of the resonance angle, etc. is extremely small. Therefore, it is very difficult to detect such a medical substance by the conventional method.

The present invention provides an apparatus for detecting a medical substance using a resonance phenomenon resonating with an evanescent wave, by which even a medical substance having a small molecular weight can be detected. Thus, a medical substance to be measured by the apparatus is previously fixed to the resonance material as an antigen; a known amount of an antibody is mixed in a sample; the antibody is brought in contact to the resonance material on which the antigen (medical substance to be detected) has been fixed; then the change of the condition for generating the resonance phenomenon (resonance angle, etc.) is observed when an antigen-antibody reaction is caused. Since an antibody has a significantly greater molecular weight, when such an antibody is coupled with the antigen (medical substance to be detected) fixed on the resonance material, the change of the condition, i.e. resonance angle, etc. is sufficiently great to be detected. It should be noted that the amount of the antibody mixed in the

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sample is previously known, so that the amount of the medical substance contained in the sample can be indirectly calculated from the change of the condition.

The Examiner asserts that "If the 'medical substance' is an antigen, then a specific binding reagent such as an antibody specific for the antigen would be required on the resonance material to provide for detection of the antigen." It is respectfully submitted that the Examiner's assertion is proper for the conventional detecting technology. However, as described above, the present invention has a feature that not an antibody but the medical substance to be detected, per se, which is an antigen, is fixed on the resonance material. This is greatly different from the conventional technology, because such construction makes it easy to detect the medical substance having a very small molecular weight! The references cited by the Examiner disclose a sensor for detecting a specific substance by using a surface plasmon resonance phenomenon. However, the substance fixed to the resonance material is not an antigen but an antibody. None of the references disclose, teach or otherwise suggest a measuring apparatus of a sensor where a medical substance (antigen) to be measured is fixed to a resonance material as recited in new independent claims 14 and 24. Further, according to the present invention, such a medical substance having an extremely small molecular weight, which has a difficulty to be detected by the conventional technique, can be easily detected and is thus clearly non-obvious over the prior art. In view of the above, Independent Claims 14 and 24, which recite the distinctive features, are allowable.

Each remaining claim is dependent, directly or indirectly, on Claims 14 and 24, and are also allowable for the same reasons.

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CONCLUSION

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance and allowance of the application is respectfully requested.

Should the Examiner require or consider it advisable that the specification, claim and/or drawings be further amended or corrected in formal respects in order to place the case in condition for final allowance, then it is respectfully requested that such amendment or correction be carried out by Examiner's Amendment and the case passed to issue. Alternatively, should the Examiner feel that the personal discussion might be helpful in advancing this case to allowance, the Examiner is invited to telephone the undersigned.

Respectfully submitted
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